UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF GEORGIA COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS LIABILITY LITIGATION	:	MDL CASE NO.: 4:08MD2004
	:	JUDGE CLAY D. LAND
HELEN N. BURGESS and ROBERT L. BURGESS,	:	CIVIL ACTION NO.: 4-13-cv-221 (CDL)
Plaintiffs,	:	
v.	:	
MENTOR WORLDWIDE LLC and MENTOR CORPORATION,	:	
Defendants.	:	

COMPLAINT

Plaintiffs Helen N. Burgess and Robert L. Burgess ("Plaintiffs") sue the Defendants, Mentor Worldwide LLC ("Mentor LLC") and Mentor Corporation ("Mentor"), collectively referred to as "Defendants," and allege as follows:

1. At all times relevant hereto, Plaintiffs were residents and citizens of the state of West Virginia. At all relevant times, Plaintiffs lived and resided together as husband and wife.

2. Defendant Mentor LLC is a Delaware Corporation with its principal place of business in Santa Barbara, California.

3. Defendant Mentor is a Minnesota Corporation with its principal place of business located in the State of California.

4. Upon information and belief, Mentor LLC has assumed the assets, rights and obligations of Mentor and as such, is responsible to the Plaintiffs for damages incurred as a result of the ObTape device implanted in Plaintiff Helen N. Burgess.

5. This action is being direct filed as a potential tag-along case to the multi-district litigation proceedings currently pending before this court, IN RE MENTOR CORP. OBTAPE TRANSOBTURATOR SLING PRODUCTS LIABILITY LITIGATION, MDL 2004, Case No. 4:08 MD 02004 CDL.

6. This action is being direct filed in the Middle District of Georgia pursuant to Judge Land's December 12, 2011 order authorizing direct filing [DE 446].

7. Plaintiffs are seeking damages in excess of $75,000.00, exclusive of interest and costs.

FACTUAL ALLEGATIONS

8. At all times material hereto, Mentor conducted business within the State of West Virginia and the District of Columbia, including maintenance of a sales force within the State of West Virginia and the District of Columbia, and manufactured, tested, analyzed, distributed, labeled, sold, supplied, marketed and/or promoted a transobturator vaginal sling product known as "ObTape" and placed said medical device into the stream of commerce.

9. Mentor began to first market its ObTape brand transobturator vaginal sling in the United States in 2003.

10. Upon information and belief, at the time that Mentor first introduced its ObTape brand transobturator vaginal sling to the market in 2003, the product had undergone inadequate pre-market testing to determine the safety and efficacy of the medical device prior to implantation in humans, and said testing was limited to animal testing (and included only three rabbits).

11. However, even the limited animal testing conducted by Mentor prior to first marketing the ObTape brand transobturator vaginal sling in 2003 had demonstrated that the medical device caused adverse tissue reactions in the rabbits.

12. Further, upon information and belief, Mentor knowingly and deliberately made material misrepresentations to the Food & Drug Administration ("FDA") concerning the safety, efficacy, design, and manufacture of its ObTape brand transobturator vaginal sling.

13. After 2003, upon information and belief, Mentor performed no additional safety or efficacy testing in human vaginal tissues to confirm that the medical device was safe and effective for use in women.

14. From 2003 through March of 2006, Mentor continued to manufacture, market, distribute, and sell this device to thousands of women even though Mentor knew that the product had been inadequately tested for safety and efficacy (both prior to and after its approval for sale in the United States), contained significant manufacturing and design defects that posed unnecessary risks to patients, and also despite knowing that numerous patients had suffered harm attributable to the defective condition of the medical device and the negligence of Mentor.

15. Prior to Plaintiff Helen N. Burgess's implantation with the ObTape device, Mentor was on notice of numerous patients who had been harmed by its ObTape brand

transobturator vaginal sling, including a significant number of women who suffered vaginal erosion, infection, extrusion, perforation and/or abscess after implantation with its device.

16. Mentor did not cease to manufacture, market, distribute, and sell its ObTape brand transobturator vaginal sling until approximately March of 2006, and even after its withdrawal of the medical device from the market due to safety issues, Mentor failed to provide adequate warnings and notice to physicians and/or patients regarding the unacceptably high rate of vaginal ObTape brand transobturator vaginal sling and the best methods for treating patients who were previously implanted with the defective devices, including Plaintiff Helen N. Burgess.

17. This failure to provide adequate warnings and information to physicians and/or patients following withdrawal of the medical device from the market in March of 2006 led to unnecessary suffering and delay in obtaining appropriate medical treatment for Plaintiff Helen N. Burgess as well as the thousands of other women who were implanted with the defective medical device.

18. On or about November 9, 2004, Plaintiff Helen N. Burgess was implanted with an ObTape brand transobturator vaginal sling designed, manufactured, packaged, labeled and sold by Mentor. The subject sling (hereinafter referred to as “the Product”) was intended to treat Plaintiff Helen N. Burgess for stress urinary incontinence, a use for which Mentor marketed the Product.

19. The Product was implanted during a procedure performed at Georgetown University Hospital in Washington, D.C. by Dr. Luis E. Sanz.

20. Plaintiff Helen N. Burgess’s treating physicians implanted the Product properly and appropriately.

21. Subsequent to these implantation surgeries, and as a direct and proximate result of the defective condition of the Product, Plaintiff Helen N. Burgess suffered serious and permanent bodily injuries, including infections, pelvic pain, exacerbation of her urinary incontinence, and the need for additional medical treatment as well as the need for extensive future medical care.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY

22. Plaintiffs incorporate by reference paragraphs 1-21 of this Complaint as if fully set forth herein.

23. This is an action for design and manufacturing defect as well as lack of an appropriate and necessary warning. Defendants are strictly liable to Plaintiffs for designing, manufacturing, marketing and/or selling a defective product.

24. The Product was expected to, and did, in fact, reach Plaintiff Helen N. Burgess without a substantial change in its condition from the time of the Product's manufacture.

25. Plaintiff Helen N. Burgess used the Product for its intended purposes and the Product was not materially altered or modified prior to its use.

26. The Product was defective and unreasonably dangerous when it left the possession of Defendants in the following manner:

a. When placed into the stream of commerce, the Product contained unreasonably dangerous manufacturing and design defects, such that it posed an unreasonable risk of harm to Plaintiff Helen N. Burgess;

b. When placed into the stream of commerce, the Product deviated materially from Defendants' design and manufacturing specifications for this particular

medical device in such a manner as to pose an unreasonable risk of harm to Plaintiff Helen N. Burgess;

c. When placed into the stream of commerce, the risks associated with the Product exceeded the benefits associated with its use;

d. The Product failed to perform as an ordinary consumer would expect when used as intended or in a manner reasonably foreseeable by Defendants;

e. Defendants failed to properly manufacture the Product with a minimum pore size of 50 microns or greater (as is necessary to ensure proper tissue in-growth following implantation), but, instead, manufactured the Product with a smaller pore size, which impaired proper tissue in-growth and resulted in an increased risk of infection, abscess formation, vaginal erosion, extrusion, and other serious harm to Plaintiff Helen N. Burgess and others;

f. The material utilized by Defendants for the construction of the Product (i.e., non-woven, microporous, inelastic polypropylene mesh) was inappropriate for use in a patient's vagina;

g. The Product contained a lack of warnings or inadequate warnings to alert Plaintiff Helen N. Burgess, her physicians, and others of severe and life threatening complications and risks associated with use of the Product including vaginal erosion, infection, extrusion, perforation, and/or abscess; and

h. The foreseeable risks of harm posed by the design of the Product could have been reduced and/or avoided by Defendants if Defendants had adopted a

reasonable alternative design, and Defendants' failure to adopt a safer alternative design rendered the Product unreasonably dangerous.

27. Defendants, as manufacturers of medical devices, are held to the level of knowledge of experts in the field.

28. Plaintiff Helen N. Burgess's physicians did not have substantially the same knowledge as Defendants or the knowledge that would have been gleaned from an adequate warning from Defendants.

29. Defendants had a continuing duty to warn Plaintiff Helen N. Burgess, her physicians, and others of the dangerous risks associated with use of the Product as well as a duty to properly manage patients who have been implanted with the Product, and failed to do so.

30. Plaintiff Helen N. Burgess and her physicians did not and could not have known at the time of her surgery in September of 2005, or any time prior, of the existence of the defective and unreasonably dangerous condition of the Product.

31. As a direct and proximate result of the Product's aforementioned defects, Plaintiff Helen N. Burgess was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

32. Defendants are liable to the Plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling the defective Product.

COUNT II: NEGLIGENCE

33. Plaintiffs incorporate by reference paragraphs 1-32 of this Complaint as if fully set forth herein.

34. Defendants had a duty to individuals, including Plaintiff Helen N. Burgess, to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Product.

35. Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Product.

36. As a direct and proximate result of Defendants' negligence, Plaintiff Helen N. Burgess was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

37. Defendants are liable to the Plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling the defective Product.

COUNT III: DESIGN DEFECT

38. Plaintiffs incorporate by reference paragraphs 1-37 of this Complaint as if fully set forth herein.

39. The Product implanted in Plaintiff Helen N. Burgess was not reasonably safe for its intended uses and was defective as a matter of law with respect to its design.

40. As a direct and proximate result of the Product's aforementioned defects, Plaintiff Helen N. Burgess was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

41. Defendants are liable to the Plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling the defective Product.

COUNT IV: MANUFACTURING DEFECT

42. Plaintiffs incorporate by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

43. The Product implanted in Plaintiff Helen N. Burgess was not reasonably safe for its intended uses and was defective as a matter of law with respect to its manufacture.

44. As a direct and proximate result of the Product's aforementioned defects, Plaintiff Helen N. Burgess was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

45. Defendants are liable to the Plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling the defective Product.

COUNT V: FAILURE TO WARN

46. Plaintiffs incorporate by reference paragraphs 1-45 of this Complaint as if fully set forth herein.

47. The Product implanted in Plaintiff Helen N. Burgess was not reasonably safe for its intended uses and was defective as a matter of law due to its lack of appropriate and necessary warnings.

48. As a direct and proximate result of the Product's aforementioned defects, Plaintiff Helen N. Burgess was caused and/or in the future will be caused to suffer severe personal

injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

49. Defendants are strictly liable to the Plaintiffs for designing, manufacturing, marketing, labeling, packaging, and selling the defective Product.

COUNT VI: BREACH OF EXPRESS WARRANTY

50. Plaintiffs incorporate by reference paragraphs 1-49 of this Complaint as if fully set forth herein.

51. Defendants made assurances to the general public, hospitals, and health care professionals that the Product was safe and reasonably fit for its intended purposes.

52. Plaintiff Helen N. Burgess and/or her health care provider chose the Product based upon Defendants' warranties and representations regarding the safety and fitness of the Product.

53. Plaintiff Helen N. Burgess, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Product was safe, merchantable, and reasonably fit for its intended purposes.

54. Defendants breached this express warranty because the Product implanted in Plaintiff Helen N. Burgess was unreasonably dangerous and defective and not as Defendants had represented.

55. Defendants' breach of their express warranties resulted in the implantation of an unreasonably dangerous and defective Product in Plaintiff Helen N. Burgess's body, placing her health and safety in jeopardy.

56. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, Plaintiff Helen N. Burgess was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT VII: BREACH OF IMPLIED WARRANTY

57. Plaintiffs incorporate by reference paragraphs 1-56 of this Complaint as if fully set forth herein.

58. Defendants impliedly warranted that the Product was merchantable and was fit for the ordinary purposes for which it was intended.

59. When the Product was implanted in Plaintiff Helen N. Burgess to treat her stress urinary incontinence, the Product was being used for the ordinary purpose for which it was intended.

60. Plaintiff Helen N. Burgess, individually and/or by and through her physician, relied upon Defendants' implied warranty of merchantability in consenting to have the Product implanted in her.

61. Defendants breached these implied warranties of merchantability because the Product implanted in Plaintiff Helen N. Burgess was neither merchantable nor suited for its intended uses as warranted.

62. Defendants' breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective Product in Plaintiff Helen N. Burgess's body, placing her health and safety in jeopardy.

63. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff Helen N. Burgess was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT VIII: LOSS OF CONSORTIUM

64. Plaintiffs incorporate by reference paragraphs 1-63 of this Complaint as if fully set forth herein.

65. As a direct and proximate result of the above-described injuries sustained by Plaintiff Helen N. Burgess, her husband, Plaintiff Robert L. Burgess, has sustained a loss of his wife's consortium, companionship, society, affection, services, and support.

COUNT IX: PUNITIVE DAMAGES

66. Plaintiffs incorporate by reference paragraphs 1-65 of this Complaint as if fully set forth herein.

67. Defendants acted with reckless indifference to the consequences that would result from their actions. The Defendants were aware, from their knowledge of existing circumstances and conditions, that their conduct would probably cause injury to Plaintiff Helen N. Burgess and others.

68. Defendants sold the Product to Plaintiff Helen N. Burgess's health care providers and other health care providers throughout the United States without conducting adequate testing to ensure that the Product was reasonably safe for implantation in the female pelvic area.

Defendants knew that their decision to not conduct adequate testing would probably cause injury to Plaintiff Helen N. Burgess and others.

69. Defendants sold the Product to Plaintiff Helen N. Burgess's health care providers and other health care providers throughout the United States without doing adequate testing to determine whether the Product degraded *in vivo*. The Product does, in fact, degrade *in vivo*, which causes the severe and debilitating injuries suffered by Plaintiff Helen N. Burgess and numerous other women. Defendants knew that their decisions to not conduct adequate testing to determine whether the Product degraded *in vivo* would probably cause injury to Plaintiff Helen N. Burgess and others.

70. Defendants acted with conscious disregard to the rights of Plaintiff Helen N. Burgess and others. The Defendants were aware, from their knowledge of existing circumstances and conditions, that their conduct would probably cause injury to Plaintiff Helen N. Burgess and others.

71. Defendants ignored reports from health care providers throughout the United States of the Product's failures to perform as intended, which lead to the severe and debilitating injuries suffered by Plaintiff Helen N. Burgess and numerous other women. Rather than conducting adequate testing to rule out the Product's design or the process by which the Product is manufactured as the causes of these severe and debilitating injuries, Defendants chose instead to instruct their sales forces to downplay the Product's risks, and continued to market and sell the Product as a safe and effective way to treat stress urinary incontinence up until and after the Product was implanted in Plaintiff Helen N. Burgess. Defendants knew that their decision to

ignore reports and continue to market and sell the Product would probably cause injury to Plaintiff Helen N. Burgess and others.

72. Defendants' conduct as described in this Complaint, for which the Plaintiffs are entitled to recover compensatory damages, manifested a conscious disregard of, and/or reckless indifference to, the consequences of their actions and the safety of those persons who might foreseeably have been harmed by the Product, including Plaintiff Helen N. Burgess, justifying the imposition of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants as follows:

a. compensatory damages on each cause of action;

b. punitive damages on each cause of action;

c. reasonable attorneys' fees where recoverable;

d. costs of this action;

e. loss of consortium, companionship, society, affection, services, and support, and;

f. such other additional and further relief as the Court may deem necessity, appropriate, and just.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and issues.

Date: July 3, 2013

/s/Kendall C. Dunson
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